Columbia Center for Children's Environmental Health

Response to August 13, 2015 EPA Request

September 3, 2015

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Maternal and Cord Chlorpyrifos Distributions: Page 4

From: "Deener, Kathleen" < Deener. Kathleen@epa.gov>

Date: August 13, 2015 at 2:58:48 PM CDT
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Subject: Follow-up from Dr. Tom Burke at EPA - chlorpyrifos

Hello Dr. Perera,

My name is Kacee Deener, and I work with Tom Burke at EPA. Tom asked me to send the information below on his behalf as a follow up to a conversation you had with him a few weeks ago. He said he will follow up with a phone call soon. I've copied Tom on this email, who with Dr. Tina Bahadori, who heads up EPA's research program on chemical safety. I've also copied Drs. Rauh and Whyatt, along with my colleague Kelley Smith, who can help facilitate a time for you to talk with Tom by phone if that's helpful.

In December 2014, EPA released a revised risk assessment for chlorpyrifos. We received over 800 public comments on the revised assessment. Some public commenters expressed concern that the 2014 risk assessment is not sufficiently health protective given the reportessociation of neurodevelopmental effects in children and the presence of low levels of chlorpyrifos in cord blood. These public commenters asked EPA to further evaluate the biomonitoring data from Columbia University to make sure the assessment protectsall lifestages. We would like to be responsive to these concerns by performing additional analyses with the biomonitoring data; however, we are limited by the information available in the journal publications. In order to conduct a more meaningful analysithat will help us understand if the assessment is sufficiently protective, we would like to understand more about the distributions of biomarker data and how biomarker levels changed with time. It would also be helpful to use the range of exposures from the canceled, indoor use as a foundation to compare and assess current exposures. Therefore, we would like to request the following information:

1. Cord Blood & Maternal Blood Levels of Chlorpyrifos

- a. We would like values at the 1st, 5th, 10th, 25th, 50th, 50th, 90th, 95th, 99th percentiles of the distribution for the data before & after the indoor cancellation. We also need the N's for the before & after cancellation data.
- b. We would like values at the 1st, 5th, 10th, 25th, 50th, 75th, 90th, 95th, 99th percentiles of the distribution for the data separated by each year of collection (ie, we need separate distributions for 1999, 2000, 2001, etc). We also need the N's for each year.

2. Urinary levels of TCPy

- a. We would like values at the 1st, 5th, 10th, 25th, 50th, 75th, 90th, 99th-percentiles of the distribution for after the indoor cancellation. Our understanding is that urinary TCPy was not measured before the cancellation. If pre-cancellation data are available, we would the that distribution also. We also need the N.
- b. We would like values at the 1st, 5th, 10th, 25th, 50th, 75th, 90th, 95th, 99th percentiles of the distribution for the data separated by each year of collection (i.e., we need separate distributions for 021, 2002, 2003, etc). We also need the N's for each year.

3. Description of Statistical Methods

a. Provide a narrative which describes the statistical approaches used to calculate each of the above distributions including specific tests used and software.

Thanks,

Kacee Deener, MPH
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Dear Tom and Kacee,

Thanks for taking the time to talk by phone with Ricky, Virginia, Lori Hoepner and me to go over this EPA request for information about chlorpyrifos distributions in our Columbia Center for Children's Environmental Health (CCCEH) New York City (NYC) cohort--it's very helpful for us to understand the context in which this request is being made. Also, we appreciate your sensitivity to our concerns about confidentiality and meaningfulness of results involving small sample sizes. Based on these considerations, we have combined data for a small number of subjects from the first and last years for which data are available (1998 and 2004) with data for adjacent years. We have also limited reporting of extreme values to the 5th and 95th percentiles.

We believe it is not helpful to attempt to aggregate all pre- and post-cancellation years, for two reasons: 1) certain women and their unborn children subsequently born 'post-cancellation' may have been exposed during gestation before the cancellation, so that samples collected in a post-cancellation birth year could reflect pre-ban exposure; 2) products containing chlorpyrifos purchased before the cancellation may have continued to be used in homes after the cancellation; 3) the cancellation process itself proceeded in phases, so there is no single time point that could be used as the cancellation date. We therefore show distributions broken down only by individual year. We believe these annual distributions, shown in the table below, clearly document the steady decrease in chlorpyrifos levels at all percentiles over time, from the starting point in 1998-1999. We believe this annual decline over time in plasma level among members of our cohort at birth is a striking demonstration of the effect of the cancellation in reducing exposure.

For cord and maternal chlorpyrifos (N=424 and 427, respectively), distributions are reported for all available years combined, and for individual years. We do not provide TCPY distributional information in this report because we believe that our 2009 EHP paper (volume 117(4): 559-567), *A Biomarker Validation Study of Prenatal Chlorpyrifos Exposure within an Inner-City Cohort during Pregnancy*, provides the most comprehensive information relevant to the current request, including results demonstrating the significant reduction in TCPY levels from 2001-2002 to 2003-2004. A copy of the 2009 paper is attached to this response.

For a full description of methods used in collecting and processing blood samples, please refer to our published papers (copies of Barr et al 2002 and Whyatt et al 2003 are attached to this response). In terms of the distributions shown in the tables below, we note that:

- All values of maternal and cord chlorpyrifos available for our CCCEH NYC cohort have been included in these distributions.
- Values below the limit of detection (LOD) are represented as one half LOD. The value of .25 pg/g that appears in the chlorpyrifos percentile distributions is one half the LOD of .50 pg/g.
- Percentile distributions were generated using the FREQUENCIES command in SPSS statistical software (version 23).

We appreciate your understanding of our need to support staff effort in fulfilling data requests like this, and your offer to expedite a service contract with the Columbia DCC for this purpose. The estimated cost of responding to the current request is \$5,000.

Please let me know if you have any questions about the attached report.

Thanks,

Howard

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Cord and Maternal CPF (pg/g) Percentiles, All Years Combined: 1998-2004

		CR_CHLOP CHLOROPYRIFOS RESULT CORD	MR_CHLOP CHLOROPYRIFOS RESULT MOTHER
N		424	427
Percentiles	5	.2500	.2500
	10	.2500	.2500
	25	.2500	.2500
	50	.5850	.5500
	75	3.8975	3.9000
	90	8.6500	7.8200
	95	12.0000	12.0000

Cord and Maternal CPF (pg/g)) Percentiles by Year: 1998-2004

MEAD M		CR_CHLOP CHLOROPYRIFOS RESULT	MR_CHLOP CHLOROPYRIFOS RESULT
YEAR_X		CORD	MOTHER
1999 (includes small # of 1998 values) N		138	72
	Percentiles 5	.2500	.8250
	10	.2500	1.5000
	25	.2500	2.6000
	50	3.7750	6.7000
	75	8.8000	9.5500
	90	12.1000	16.0000
	95	15.0500	19.3500
2000	N	110	120
	Percentiles 5	.2500	.2500
	10	.2500	.2500
	25	1.6125	1.3325
	50	2.5200	3.8000
	75	4.3250	5.8000
	90	6.2900	9.1500
	95	8.8100	12.9500
	N	71	86
	Percentiles 5	.2500	.2500
	10	.2500	.2500
	25	.2500	.2500
	50	.2500	.2500
	75	.5800	.8675
	90	2.4460	2.4410
2002	95 N	2.5820 37	2.6125 60
	Percentiles 5	.2500	.2500
	10	.2500	.2500
	25	.2500	.2500
	50	.2500	.2500
	75	.9050	1.0950
	90	2.3700	2.2360
	95	2.5720	2.4975
2003 (includes small # of 2004 values) N		68	89
Percentiles 5		.2500	.2500
	10	.2500	.2500
	25	.2500	.2500
	50	.2500	.2500
	75	.2500	.2500
	90	.2500	.2500
	95		
	93	.2500	.2500